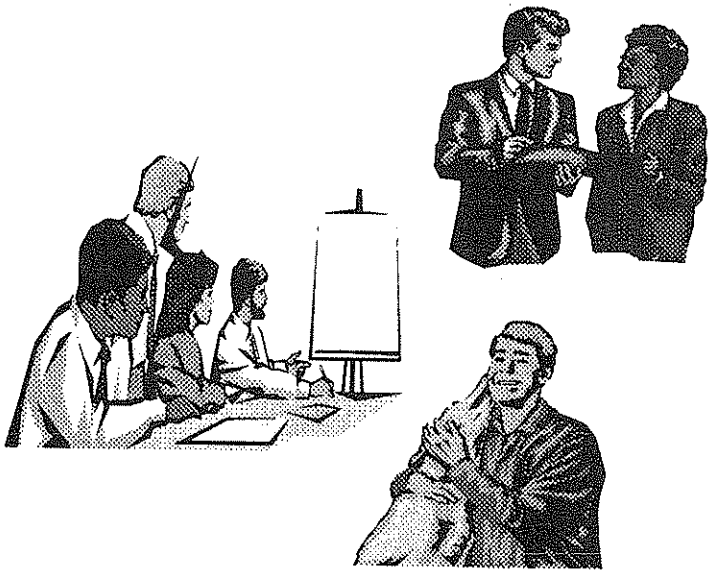
PSYCHOPHARMACOLOGICAL MEDICATIONS

Safety Precautions for Persons with Developmental Disabilities



A Resource for Training and Education

By the
Health Care Financing Administration
Health Standards and Quality Bureau
Center for Long Term Care

NOTE: Although the Social Security Act refers to Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), and uses the term "mentally retarded"; most now prefer the terms "Facilities for Persons with Developmental Disabilities" and "Persons with Developmental Disabilities".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

Dear ICF/MR Administrator:

We are sending you this document, entitled "Psychopharmacological Medication, Safety Precautions for Persons with Developmental Disabilities; A Resource for Training and Education" to assist you and your staff in increasing the benefit from psychopharmacological medications while minimizing the harm that they sometimes can cause. We are sending "Safety Precautions" to the Administrators of all Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) and all State survey agencies.

These "Safety Precautions" have been developed over a period of years by the Health Standards and Quality Bureau with input from physicians and pharmacists who have experience and training with persons who suffer from developmental disabilities and mental illness. These "Safety Precautions" represent common sense steps for protecting your clients from the sometimes significant and long lasting adverse drug reactions from psychopharmacological medications. Please give these "Safety Precautions" serious consideration.

The use of psychopharmacological medications can be therapeutic and empowering for someone who is suffering from mental illness. Therefore, the primary goal of these "Safety Precautions" is to encourage the accurate differential diagnosis of behavioral and psychiatric symptoms so that the person's treatment is appropriate.

But psychopharmacological medications should not be used when a behavioral disturbance is caused by an environmental stressor (e.g., excessive heat, noise, overcrowding, etc.), a psychosocial stressor (e.g., abuse, taunting, teasing, etc.), or a treatable non-psychiatric medical condition (e.g., heart disease, diabetes, hypothyroidism, etc.). **All** facility staff should search for the basic cause or reason for behavioral or psychiatric symptoms and endeavor to treat the basic cause or reason in the least intrusive most positive way.

These "Safety Precautions" may also alert the State agency surveyor to a situation when a psychopharmacological medication should be used when it is not. For example, a person may be suffering from symptoms of depression (e.g., withdrawal behavior, crying, etc.), yet has never been evaluated for the condition of depression and the possible use of psychopharmacological medications. While surveyors are not trained as psychiatrists, they should be alert to this potential situation and should be ready to encourage compliance with 42 CFR 483.460(a)(3) which requires the facility to arrange or provide for preventive or general physician care. Hopefully, this care is provided by a psychiatrist or a practitioner who is in consultation with a psychiatrist.

Although psychopharmacological medications were once used to sedate persons with developmental disabilities, today many facilities around the country use more enlightened practices. Psychiatrists with knowledge and experience in treating persons with developmental disabilities can more accurately diagnose and effectively treat mental illness in people with developmental disabilities. However, the differentiation of signs representing mental illness from behavioral disturbance or other conditions where treatments other than the use of psychopharmacological medications may be appropriate often remains a difficult task because persons with developmental disabilities frequently do not have verbal language skills.

The need for knowledge in this field is the fundamental reason the Nisonger Center convened an International Consensus Conference on Psychopharmacology in June, 1995, at The Ohio State University. The Conference proceedings, an extensive consensus from the best minds in the fields of psychopharmacology and developmental disabilities, discuss general principles of differential diagnosis in persons with developmental disabilities who suffer from mental illness and include chapters on each major category of psychopharmacological medication. The proposed title of these proceedings is Psychotropic Medication and Developmental Disabilities: The International Consensus Handbook. This consensus document will be published and available in early 1997. To obtain this handbook, write or call:

Nisonger Center
The Ohio State University
1581 Dodd Drive
Columbus, Ohio 43210-1296
Phone: (614) 292-8365
Fax: (614) 292-3727

The "Safety Precautions" in this document focus on surveyor and provider education and the relationship between principles of psychopharmacological and the regulations governing participation of facilities in the Medicaid program. These "Safety Precautions" are compatible with the Nisonger Handbook. The use of both will serve to build practices, skills, and experiences that will create a safer and more empowering environment for persons with developmental disabilities. For these reasons we hope that you will give these "Safety Precautions" your careful consideration.

If you have any questions about the "Safety Precautions" please refer them to Dr. Samuel W. Kidder, at (410) 786-6795. And please help us by completing the evaluation form following this letter.

Sincerely,

Richard W. Besdine, M.D.
Director
Health Standards and Quality Bureau

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PROVIDER EVALUATION

Psychopharmacological Medications: **Safety Precautions** for Persons with Developmental Disabilities

A Resource for Training and Education

After you have read the "**Safety Precautions,**" please complete this evaluation. This evaluation may be copied and given to others in your facility for comment. If you, or any staff, have additional comments or insights, please add these to the evaluation.

I. Have you shared, or do you plan to share, these "**Safety Precautions**" with:
(If any categories do not apply, please respond with "**N/A** ".)

	Yes	No	
A.	____	____	Your **direct care staff**?
B.	____	____	The **Qualified Mental Retardation Professional** (QMRP)?
C.	____	____	The **nurses** who serve your client(s)?
D.	____	____	The **physicians** who serve your client(s)?
E.	____	____	The **specially constituted committee**?
F.	____	____	The **interdisciplinary team**?

II. Will you use these "**Safety Precautions**" to conduct inservice training for:
(If any categories do not apply, please respond with "**N/A**".)

	Yes	No	
A.	____	____	Your **direct care staff**?
B.	____	____	The **Qualified Mental Retardation Professional** (QMRP)?
C.	____	____	The **nurses** who serve your client(s)?
D.	____	____	The **physicians** who serve your client(s)?
E.	____	____	The **specially constituted committee**?
F.	____	____	The **interdisciplinary team?**

III. Do you think that these "**Safety Precautions**" will help you:

	Yes	No	
A.	____	____	identify clients who *may be* in need of psychopharmacological medications?
B.	____	____	identify clients who are experiencing adverse effects from psychopharmacological medications?

FOLD

C.	____	____	identify clients' behavioral disturbances that *may be caused* by the adverse effects of psychopharmacological medications?
D.	____	____	identify changes in environmental or psychosocial circumstances that would be less restrictive and more positive interventions for your clients' behavioral disturbances than the use of psychopharmacological medications?

IV. What state is your facility located in?

_____

Thank you for the time and thought you have given in completing this evaluation of "**Safety Precautions**". Please fold this page in thirds, seal it, and mail it to:

FOLD

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Samual W. Kidder, Pharm.D., MPH
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Charts, Lists, and Tables

Charts, Lists, and Tables . . . continued

PART I.

General Safety Precautions for Psychopharmacological Medications

For a facility to use psychopharmacological medications with optimal safety, it should adhere to the **General Safety Precautions** in this section and the **Specific Safety Precautions** unique to the medication categories in **Part II**.

General Safety Precautions for Psychopharmacological Medications in ICFs/MR

1. Rule Out Other Causes
2. Collect Baseline Data
3. State a Reasonable Hypothesis
4. Intervene in the Least Intrusive and Most Positive Way
5. Monitor for Adverse Drug Reactions (ADRs)
6. Collect Outcome Data
7. Start Low and Go Slow
8. Periodically Consider Gradual Dose Reduction
9. Maintain Active Treatment Objectives
10. Maintain Optimal Functional Status

The Surveyor should apply these **General Safety Precautions** to all categories of psychopharmacological medications in **Part II**. An explanation of each **General Safety Precaution** follows.

1. Rule Out Other Causes

Before beginning psychopharmacological medication, the facility has substantial information to demonstrate that it considers and rules out other reasons such as medical, environmental, or psychosocial causes for the behavioral or psychiatric symptom.

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an accurate and comprehensive functional assessment.
42 CFR 483.440(c)(4) requiring an individual program plan . . . to meet the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh the potentially harmful effects of the drug.

2. Collect Baseline Data

Before beginning psychopharmacological medication, the facility has substantial information to demonstrate that it collects baseline data* on specific objectively defined target behaviors or psychiatric symptoms for a sufficient time** of two to four weeks.

If the person has recently been transferred to the facility and baseline data is not available, the facility does not have to remove the person from the psychopharmacological medication to obtain baseline data. Instead the facility should try to obtain the baseline data from the previous facility **if possible*** and begin collecting new data with the current psychopharmacological medication at the current dose to evaluate subsequent changes.

* In determining the baseline, the facility should use a recognized objective data collection method such as a frequency count, duration recording, time sample, interval recording, rating scale, or some combination involving these methods.

** If the facility uses a shorter time period, it must have justifying documentation which ensures, at a minimum, that variables such as transitory outbursts ("a bad day"), the environment, or illness have not resulted in a deceptively high or an unrepresentative rate of the occurrence of signs or symptoms.

*** It may not always be possible to obtain baseline data from the previous facility due to factors such as the person or guardian refusing to release such information or the previous facility failing to collect such information.

One **Exception** to this **General Safety Precaution** is the collecting of baseline data for recurrent behaviors. Refer to the box on the next page.

➡ Exception: Baseline Data for Recurrent Behaviors

If outcome data is available to show that previous treatment was successful,
and the outcome data was collected in the person's current environment,
and no major changes* have occurred within that environment,
and the behavior recurs within six months;

Then previously collected baseline data may be used for the recurrent behavior
and the facility does not have to collect new baseline data.

* Examples of major changes are where the person's daily activity schedule has been significantly reorganized, where behavioral or psychiatric or active treatment programs have been revised, etc.

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an assessment.
42 CFR 483.440(c)(4) requiring an individual program plan to deal with the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh harmful effects of the drug.

3. State a Reasonable Hypothesis

The facility has stated a reasonable hypothesis of the underlying cause of the behavioral or psychiatric symptoms. This hypothesis includes the relationship or rationale between the person's symptoms and how the prescribed psychopharmacological medication will treat these symptoms to achieve the desired outcome.

REGULATORY BASIS:
42 CFR 483.450(e)(2) requiring that medications only be used when an integral part of an individual program plan directed specifically toward reduction or elimination of behaviors for which the medications are used.

4. Intervene in the Least Intrusive and Most Positive Way

The facility has substantial information to demonstrate that it attempted the least intrusive and most positive interventions* to manage behavioral or psychiatric symptoms before it considered using psychopharmacological medication.

* Examples of least intrusive and most positive interventions are active treatment programs incorporating psychotherapy or educational programs specific to the presenting problem, and positive reinforcement procedures and other learning and behavior modification procedures such as
- antecedent analyses
- fading
- forward or backward chains
- shaping
- specific program steps with criteria levels for advancement or remedial branching
- stimulus control
- task analysis

See **Definitions**.

➦ Note: PSYCHOPHARMACOLOGICAL MEDICATION

Initially, the least intrusive and most positive intervention to treat behavioral or psychiatric symptoms may be the use of a psychopharmacological medication.

However,

all **General** and **Specific Safety Precautions** should be applied

and

once the symptoms are managed, non-psychopharmacological active treatment programs specific to the behavior or psychiatric condition should be started within a reasonable period* of time.

* A reasonable period of time is one to four weeks unless the facility justifies a longer period.

REGULATORY BASIS:
42 CFR 483.450(b)(1)(iii) requiring least restrictive most positive interventions.

5. Monitor for Adverse Drug Reactions (ADRs)

The facility has substantial information to demonstrate that it adequately monitors* for adverse drug reactions. If ADRs do occur, the facility has substantial information to show why the ADR is not significantly impairing the person's functional status or quality of life or why the psychopharmacological medication is not changed, discontinued, or decreased in dose.

* The term "adequately monitors" includes the periodic assessment of the person with a standardized side effects rating scale or checklist such as the
- Adverse Drug Reaction (ADR) Detection Questionnaire, **or**
- Monitoring of Side Effects Scale (MOSES), **or**
- Systematic Assessment for Treatment of Emergent Effects (SAFTEE), **or**
- Dosage Record and Treatment Emergent Symptom Scale (DOTES).

See **Definitions**.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

6. Collect Outcome Data

The facility has substantial information, including quality of life information, to demonstrate that it determines and supports with objective data that the psychopharmacological medication achieves the desired outcome. Objective data includes the use of a recognized data collection method* for the person's target behavior(s) or psychiatric symptom(s) and comparison to the available baseline data.

* In determining the outcome, the facility should use a recognized data collection method such as a frequency count, duration recording, time sample, interval recording, rating scale, or some combination of these methods. See **Definitions**.

REGULATORY BASIS:
42 CFR 483.450(e)(2) requiring that medications only be used when an integral part of an individual program plan directed specifically toward reduction or elimination of behaviors for which the medications are used.

7. Start Low and Go Slow

The facility has substantial information to demonstrate that it uses low initial and maintenance doses of psychopharmacological medication commensurate with age, weight, and symptomatology to achieve the desired outcome, minimize adverse drug reactions, and maintain optimal functional status.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring lowest possible dose.

8. Periodically Consider Gradual Dose Reduction

The facility has substantial information to demonstrate that **unless clinically contraindicated** it periodically attempts to gradually reduce the dose of psychopharmacological medication to determine if the person's behavioral or psychiatric symptoms can be treated with a lower dose or whether the psychopharmacological medication can be discontinued altogether. Any attempt to reduce the dose should be coordinated with the interdisciplinary team, in a carefully monitored program.

The **Exception** to this **General Safety Precaution** is the diagnosis of epilepsy. When the person is diagnosed with epilepsy, **do not** apply this **General Safety Precaution**. Instead apply the **Specific Safety Precaution, "Reassess the Need for the AED after Two Years of Seizure Free Therapy"**, on page 45.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisplinary team, unless clinically contraindicated.

9. Maintain Active Treatment Objectives

The facility has substantial information supported with objective data to demonstrate that the psychopharmacological medication is not causing the person to regress or to fail to progress in achieving the stated objectives in the individual program plan in comparison with measurements taken before and after psychopharmacological medication is started.

REGULATORY BASIS:
42 CFR 483.440(a)(1)(ii) requiring that active treatment be directed toward "the prevention or deceleration of regression, or loss of current optimal functional status".
42 CFR 483.440(f)(1)(i),(ii), and (iii) requiring an annual review of the client's progress in achieving individual program plan objectives.

10. Maintain Optimal Functional Status

The facility has substantial information, supported with objective data, to demonstrate that the psychopharmacological medication is **not diminishing** the person's functional status from his/her baseline functional status measures. See **Definitions** for the definition of functional status. Also see page 50, "Loss of Functional Status".

REGULATORY BASIS:
42 CFR 483.440(a)(1)(ii) requiring that active treatment be directed toward "the prevention or deceleration of regression, or loss of current optimal functional status."

Two terms, "substantial information to demonstrate" and "clinically contraindicated" were used frequently in this section. These terms are explained here. Other significant terms used throughout the **General** and **Specific Safety Precautions** are explained under **Definitions**.

What does "substantial information to demonstrate" mean?

"Substantial information to demonstrate" does not simply mean that the order for the psychopharmacological medication includes a diagnostic label. "Substantial information to demonstrate" means that the physician has a valid clinical reason for using this psychopharmacological medication as evidenced by your evaluation of some, but not necessarily all, of the following:

- data on specifically defined target behaviors
- individual assessment
- interview of the direct care staff, family, other residents, and similar information
- plan of care
- laboratory reports
- medication orders
- observation and interview with the client
- professional consultations
- progress notes
- reports of significant change

What does "clinically contraindicated" mean?

"Clinically contraindicated" means that the facility:

a. provides a description of previous gradual dose reduction failures **or**

b. fully supports why the continued use of the psychopharmacological medication and the dose of the psychopharmacological medication is clinically appropriate and not clinically contraindicated as demonstrated by the following four elements:

1. **Symptomatology** is a thorough description of individual symptoms and not simply a diagnostic label or a diagnostic code.

2. **Differential Diagnosis** is a discussion of the differential medical symptoms, including psychiatric symptoms. For example, why is the person's aggression part of a psychosis and not the result of pain or of psychosocial and environmental stressors?

3. **Choice of Treatment** is a description of the reasoning for the choice of a particular treatment or treatments.

4. **Dose Level** is a discussion of why the present dose is necessary to manage the person's symptoms.

PART II.

SPECIFIC SAFETY PRECAUTIONS FOR CERTAIN CATEGORIES of PSYCHOPHARMACOLOGICAL MEDICATIONS

Note: For the purposes of this document the **generic** drug name is used first followed by the **trade** name in parenthesis, for example: diazepam (Valium).

PART II

Specific Safety Precautions for Certain Categories of Psychopharmacological Medications

A. Medications Used for Anxiety and/or Insomnia

1. What Are Benzodiazepine Medications?

Benzodiazepine (ben-zoe-dye-AZ-e-peen) medications belong to the group of medicines called central nervous system (CNS) depressants. CNS depressants are medications that lower the activity of the central nervous system. For example, CNS depressants reduce alertness and cognition. Benzodiazepine medications are used for various conditions such as anxiety, panic disorder, epilepsy, insomnia (sleepnessness), and muscle spasms. Each of these conditions is discussed below:

Anxiety. Some benzodiazepine medications are classified as anxiolytic (anxiety-decreasing) medications. The following benzodiazepine medications are primarily used to relieve anxiety or nervousness.

Generic Name:	chlordiazepoxide	diazepam	lorazepam	oxazepam
Trade Name:	Librium	Valium	Ativan	Serax

Another benzodiazepine medication, alprazolam (Xanax), is used to treat panic disorder. **Panic disorder** is a unique form of anxiety.

Epilepsy. Although there is little evidence that benzodiazepine medications are effective for the long term treatment of epilepsy in most individuals, in some cases certain benzodiazepine medications are used in treating epilepsy. For further information about epilepsy and the medications used to treat it, see pages 41 and 42, "**4. Epilepsy and the Use of Antiepileptic Drugs**" and "**5. Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Epilepsy**".

Insomnia (sleeplessness). The benzodiazepine medications are usually not effective for insomnia for more than a few weeks. The following benzodiazepine medications are used in the treatment of insomnia.

Generic Name:	flurazepam	temazepam	triazolam
Trade Name:	Dalmane	Restoril	Halcion

Muscle Spasm. Some benzodiazepine medications are also used for muscle spasms. Diazepam (Valium) is used to relax muscles or to relieve muscle spasm.

2. Anxiety

a. What Is Anxiety ?

An anxiety disorder may manifest itself as a behavioral or a psychiatric symptom. Anxiety can be a symptom for a wide variety of non-psychiatric medical problems such as cardiac ischemia or ulcers.

Stedman's Medical Dictionary defines anxiety as follows: "Apprehension of danger and dread accompanied by restlessness, tension, tachycardia, and dyspnea unattached to a clearly identifiable stimulus." Note that in this definition, the individual has clear physiological symptoms such as tachycardia (fast heart rate) or dyspnea (shortness of breath) and that these symptoms occur without any clear reason. The origin or cause for these physiological symptoms are especially difficult to determine in people with nonexistent or limited verbal language skills. This is why the first **General Safety Precaution**, **"Rule Out Other Causes"**, is particularly important in persons with developmental disabilities.

b. Anxiety and the Use of Benzodiazepine Medications

Before considering the use of any medication for anxiety, it is **essential to evaluate the medical, psychosocial, and environmental causes for anxiety**. There are times when it is appropriate for a person to be anxious. For example, if a person is being abused or humiliated, it is not appropriate to use medication to make the person less anxious and more compliant with abuse. Failure to evaluate causes such as these makes the use of benzodiazepine medications, or any other medications for anxiety, inappropriate.

Often, anxiety is treated well without medications. However, treatment may require a combination of both pharmacologic and non-pharmacologic interventions. Medications can easily be overused if a person does not have a comprehensive intervention program for anxiety which includes relaxation, appropriate counseling, and/or reduction of environmental stress.

c. Specific Safety Precautions for Benzodiazepine Medications Used for Anxiety

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to benzodiazepine medications used for anxiety.

1. Monitor for Adverse Drug Reactions (ADRs) from the Benzodiazepine Medication Used for Anxiety

2. Screen for Higher Doses of the Benzodiazepine Medication Used for Anxiety

3. Consider Gradually Reducing the Dose of the Benzodiazepine Medication Used for Anxiety

The greater the inability of the facility to follow each **General** and **Specific Safety Precaution**, the greater the potential risk of harm to the person being treated, and the greater the propensity for the surveyor to judge the drug therapy as unnecessary. If the **General** and **Specific Safety Precautions** are **not** followed, offer the facility an opportunity to explain why it was unable to carry out these protection activities.

Three **Exceptions** to these **Specific Safety Precautions** are explained on pages 21 and 22.

1. Monitor for Adverse Drug Reactions (ADRs) from the Benzodiazepine Medication Used for Anxiety

The facility has substantial information to demonstrate that it adequately monitors the person for any adverse drug reaction (ADR) from a benzodiazepine medication used for anxiety. If these ADRs do occur, the facility has substantial information to demonstrate why the ADR does not significantly impair the person's functional status or quality of life or why the medication was not changed, discontinued, or decreased in dose.

Adverse Drug Reactions (ADRs) from Benzodiazepine Medications

- Continuing Slurred Speech
- Decreased Reflexes
- Disinhibition (Lack of Impulse Control)
- Dysphagia (Difficulty in Swallowing)
- Hyperactivity
- Shortness Breath or Trouble Breathing
- Impaired Learning
- Persistent Confusion
- Severe Drowsiness
- Severe Weakness
- Staggering / Falls

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication exacerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

2. Screen for Higher Doses of the Benzodiazepine Medication Used for Anxiety

The facility has a reasonable explanation that justifies why doses **greater** than those listed in the screen below are necessary to improve or maintain the person's functional status.

SCREEN FOR HIGHER DOSES OF BENZODIAZEPINE MEDICATIONS USED FOR ANXIETY

These dose levels are given to establish a point at which higher doses should be explained. If the person is prescribed a higher dose than shown, the facility should explain the specific clinical circumstances requiring the higher dose.

GENERIC	TRADE	DAILY ORAL DOSE* (in milligrams)	
		Adults	Geriatric or Child under 12
alprazolam	Xanax	2	1
chlordiazepoxide	Librium	40	20
clonazepam	Klonopin	3	1.50
clorazepate	Tranxene	30	15
diazepam	Valium	20	10
halazepam	Paxipam	100	40
lorazepam	Ativan	6	2
oxazepam	Serax	60	30
prazepam	Centrax	30	15

* **These are not maximum doses!** When higher doses are prescribed, the facility should explain in the clinical record the unique circumstances which require the higher dose.

Appropriate clinical doses vary greatly depending on the individual signs or symptoms, age, weight, and other factors. Doses lower than these are often adequate to achieve the desired outcome for the person.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring the lowest possible dose.

3. Consider Gradually Reducing the Dose of the Benzodiazepine Medication Used for Anxiety

The facility has substantial information to demonstrate that **unless clinically contraindicated*** it periodically attempts to gradually** reduce the dose of the benzodiazepine medication to determine if the person's behavioral or psychiatric symptom can be helped with a lower dose, or to determine if the medication can be discontinued altogether.

The facility should attempt to reduce the dose of benzodiazepine medication, in a carefully monitored program, within **four** months or less of therapy, and at least annually thereafter, **unless clinically contraindicated**. This attempt should be coordinated with the interdisciplinary team in a carefully monitored program.

* **Clinically contraindicated** is defined on page 9.

** Gradually reducing the dose is **especially important** in withdrawal of benzodiazepine medications because rapid reductions may result in more serious withdrawal symptoms. Gradual dose reduction is generally accomplished by reducing the dose by 25% every 1 to 4 weeks depending on the duration of the dose, age, symptoms, weight, and other factors.

Adhering to this recommendation for dose reduction is **even more important** if the person has been using a short-acting benzodiazepine medication in a high dose for an extended period of time.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisciplinary team, unless clinically contraindicated.

d. Exceptions to the Specific Safety Precautions for Benzodiazepine Medications Used for Anxiety

When a benzodiazepine medication is used for the following conditions, it should not be reviewed under the **Specific Safety Precautions** unique to benzodiazepine medications used for anxiety, page 17.

1. **Dental, Medical, or Surgical Procedures**
2. **Muscle Spasm**
3. **Seizure Disorder or Status Epilepticus**

Exception 1: Dental, Medical, or Surgical Procedures

These **Specific Safety Precautions** do not apply when the medication is given in a single dose to relieve anxiety or to produce amnesia before a dental, medical, or surgical procedure.

Exception 2: Muscle Spasm

These **Specific Safety Precautions** do not apply if diazepam (Valium) or clonazepam (Klonopin) is used to treat muscle spasm. If one of these medications is used to treat a muscle spasm, the clinical record should substantiate that the person has a condition such as:

1. **muscle spasm** secondary to inflammation of muscles or joints or trauma,
2. **spasticity** caused by upper motor neuron disorder such as cerebral palsy or paraplegia,
3. **tardive dyskinesia** caused by antipsychotic medications, or
4. **athetosis**.

If the condition is **not** substantiated in the clinical record, or the dose is being changed based on behavioral or psychiatric symptoms, then **presume** that the medication is being used to treat an anxiety disorder and apply the "**Specific Safety Precautions for Benzodiazepine Medications Used for Anxiety**" on page 17.

Exception 3: Seizure Disorder or Status Epilepticus

These **Specific Safety Precautions** do not apply if diazepam (Valium), chlorazepate (Tranzene), lorazepam (Ativan), or clonazepam (Klonopin) is being used to treat seizure disorder or status epilepticus. If seizure disorder or status epilepticus is being treated, follow the "**Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Epilepsy** " on page 42.

3. INSOMNIA

a. What Is Insomnia?

Insomnia is the inability to sleep in the absence of external impediments such as noise, or bright lights, during a period of time that one normally sleeps. Insomnia is not necessarily a pathological circumstance. Everyone occasionally has difficulty in sleeping. There are many causes of insomnia and many approaches to treatment.

The long term use of benzodiazepine medication and other hypnotic drugs to treat transient insomnia can result in dependency. The term "hypnotic" means sleep inducing. The key to managing insomnia is to:

1. **Rule out all causes of insomnia**. See page 26.

2. Follow good sleep hygiene practices. See "**For a Good Night's Sleep**" on the following page.

3. Refrain from using hypnotics for transient insomnia.

4. When a hypnotic must be used, only use it for a short period of time.

For a Good Night's Sleep z z z

z z z z z z z z z z z z z....

DO

Exercise today, but not too late in the evening ☺

Develop a sleep ritual ☺

Go to bed at your usual time every night ☺

Relax before bedtime by reading or taking a hot bath ☺

Sleep in a cool, dark, quiet bedroom ☺

Wake up at the usual time every morning ☺

DO NOT

Take naps during the day ☹

Drink alcoholic beverages or smoke, especially near bedtime ☹

Consume beverages with caffeine: coffee, or tea and many soft drinks, especially near bedtime ☹

Eat foods that contain caffeine, such a chocolate ☹

Go to bed stuffed or starved ☹

Go to bed too early☹

Adapted from "*The Good Night Guide*", © 1993, with permission of The Better Sleep Council.

b. Insomnia and Use of Benzodiazepine and Other Medications

Any benzodiazepine medication and many antihistamines, whether marketed as a hypnotic (sleep-inducing) medication or not, can be used to induce sleep. For the generic and trade names of benzodiazepine medications and other sleep inducing medications, please refer to page 28, "**Screen for Higher Doses of Benzodiazepine And Other Medications Used for Insomnia**".

c. Specific Safety Precautions for Benzodiazepine and Other Medications Used for Insomnia

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to benzodiazepine and other medications used for insomnia.

1. **Rule Out Other Causes for Insomnia**
2. **Collect Baseline Data on the Occurrence of Insomnia**
3. **Manage Insomnia in the Least Intrusive and Most Positive Way**
4. **Monitor for Adverse Drug Reactions (ADRs) from the Medication Used for Insomnia**
5. **Screen for Higher Doses of the Medication Used for Insomnia**
6. **Periodically Consider Gradually Reducing the Dose of the Medication Used for Insomnia**

The greater the inability of the facility to follow each **General** and **Specific Safety Precaution**, the greater the potential risk of harm to the person being treated, and the greater the propensity for the surveyor to judge the drug therapy as unnecessary. If the **General** and **Specific Safety Precautions** are **not** followed, offer the facility an opportunity to explain why it was unable to carry out these protection activities.